



General

Guideline Title

Osteoporosis in men: an Endocrine Society clinical practice guideline.

Bibliographic Source(s)

Watts NB, Adler RA, Bilezikian JP, Drake MT, Eastell R, Orwoll ES, Finkelstein JS. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012 Jun;97(6):1802-22. [203 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [October 25, 2016 – Testosterone and Other Anabolic Androgenic Steroids \(AAS\)](#) : The U.S. Food and Drug Administration (FDA) approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (+OOO, ++OO, +++O, and ++++); the strength of the recommendation (1 or 2); and the difference between a "recommendation" and a "suggestion" are provided at the end of the "Major Recommendations" field.

Evaluation

The Task Force suggests testing men at increased risk for osteoporosis by measurement of bone mineral density (BMD). Age 70 is a sufficient risk factor. Younger men (aged 50–69) should be tested if additional risk factors are present. A history of fracture after age 50 is a particularly important indication for evaluation. Other reasons for testing men aged 50–69 include diseases/conditions such as delayed puberty, hypogonadism,

hyperparathyroidism, hyperthyroidism, or chronic obstructive pulmonary disease; drugs such as glucocorticoids or gonadotropin-releasing hormone (GnRH) agonists; life choices such as alcohol abuse or smoking; or other causes of secondary osteoporosis. FRAX, Garvan, or other fracture risk calculators can improve the assessment of fracture risk and the selection of patients for treatment. (2|++OO)

The Task Force recommends dual-energy x-ray absorptiometry (DXA) of the spine and hip in men at risk for osteoporosis. (1|++OO)

The Task Force suggests measuring forearm DXA (1/3 or 33% radius) when spine or hip BMD cannot be interpreted and for men with hyperparathyroidism or receiving androgen-deprivation therapy (ADT) for prostate cancer. (2|++OO)

The Task Force suggests a complete history and physical examination for men being evaluated for osteoporosis or considered for pharmacological treatment (e.g., those with low BMD and/or high fracture risk). Important information includes medications used, chronic diseases, alcohol or tobacco abuse, falls and/or fractures as an adult, and family history of osteoporosis. Physical examination should assess patient height in comparison with maximum height, kyphosis, balance, mobility, overall frailty, and evidence of causes of secondary osteoporosis, including testicular atrophy, signs of hyperthyroidism, and evidence of chronic obstructive pulmonary disease. Men for whom bisphosphonate therapy is considered should have an examination of the teeth. (2|++OO)

The Task Force suggests measuring serum calcium, phosphate, creatinine (with estimated glomerular filtration rate), alkaline phosphatase, liver function, 25-hydroxyvitamin D (25[OH]D), total testosterone, complete blood count, and 24-h urinary calcium (creatinine and sodium) excretion in men being evaluated for osteoporosis or considered for pharmacological treatment with bone-active agents. (2|++OO)

If history or physical examination suggests a specific cause of osteoporosis, further testing should be done. Depending on the findings of the history and physical examination, such testing may include (but is not limited to) calculated free or bioavailable testosterone (using measurements of sex hormone-binding globulin [SHBG]), serum protein electrophoresis with free κ and λ light chains and/or urine protein electrophoresis, tissue transglutaminase antibodies (for celiac disease), thyroid function tests, and parathyroid hormone (PTH) levels. (2|++OO)

In men with low bone mass (osteopenia) or osteoporosis who might have previously undiagnosed vertebral fractures, the Task Force recommends vertebral fracture assessment (VFA) using DXA equipment. If VFA is not available or is technically limited, lateral spine radiographs should be considered. (1|++OO)

Lifestyle

The Task Force recommends that men with or at risk for osteoporosis consume 1000–1200 mg calcium daily, ideally from dietary sources, with calcium supplements added if dietary calcium is insufficient. (1|+++O)

The Task Force suggests that men with low vitamin D levels (<30 ng/ml [75 nmol/liter]) receive vitamin D supplementation to achieve blood 25(OH)D levels of at least 30 ng/ml (75 nmol/liter). (2|+++O)

The Task Force suggests that men at risk of osteoporosis participate in weight-bearing activities for 30–40 min per session, three to four sessions per week. (2|+OOO)

The Task Force suggests that men at risk of osteoporosis who consume three or more units of alcohol per day reduce their alcohol intake. (2|+OOO)

The Task Force recommends that men at risk of osteoporosis who smoke cease smoking. (1|++OO)

Treatment

Selection of Men for Treatment

All Men

The Task Force recommends pharmacological therapy for men at high risk for fracture including, but not limited to:

- Men who have had a hip or vertebral fracture without major trauma. (1|+++O)
- Men who have not experienced a spine or hip fracture but whose BMD of the spine, femoral neck, and/or total hip is 2.5 standard deviations (SD) or more below the mean of normal young white males. (1|++OO)
- In the United States, men who have a T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture $\geq 20\%$ or 10-yr risk of hip fracture $\geq 3\%$ using FRAX; further studies will be needed to determine appropriate intervention levels using other fracture risk assessment algorithms. For men outside the U.S., region-specific guidelines should be consulted. (1|++OO)
- Men who are receiving long-term glucocorticoid therapy in pharmacological doses (e.g., prednisone or equivalent >7.5 mg/d), according to

the 2010 guidelines of the American Society of Rheumatology. (1|++OO)

Selection of Therapeutic Agent

The Task Force recommends that men at high risk of fracture be treated with medication approved by regulatory agencies such as the U.S. Food and Drug Administration (FDA) or the European Union (EU) European Medicines Agency (EMA) (at the time of this writing, alendronate, risedronate, zoledronic acid, and teriparatide; also denosumab for men receiving ADT for prostate cancer) and that the selection of therapeutic agent be individualized based on factors including fracture history, severity of osteoporosis (T scores), the risk for hip fracture, patterns of BMD (i.e., whether BMD is worse at sites where cortical bone [e.g., 1/3 radius] or trabecular bone [e.g., spine] predominate), comorbid conditions (e.g., peptic ulcer disease, gastroesophageal reflux, malabsorption syndromes, malignancy, etc.), cost, and other factors. In men with a recent hip fracture, the Task Force suggests treatment with zoledronic acid. When teriparatide is administered, the Task Force suggests that it not be given with concomitant antiresorptive therapy. Agents that have not been approved by regulatory agencies for treatment of osteoporosis in men (calcitonin, ibandronate, strontium ranelate, etc.) should be used only if the approved agents for male osteoporosis cannot be administered. (1|++OO)

Management of Hypogonadal Men at High Risk of Fracture

For men at high risk of fracture who are receiving testosterone therapy, the Task Force suggests adding an agent with proven antifracture efficacy (e.g., a bisphosphonate or teriparatide). (2|+OOO)

The Task Force suggests testosterone therapy in lieu of a "bone drug" for men at borderline high risk for fracture who have serum testosterone levels below 200 ng/dl (6.9 nmol/ liter) on more than one determination, if accompanied by signs or symptoms of androgen deficiency (e.g., low libido, unexplained chronic fatigue, loss of body hair, hot flashes, etc.) or "organic" hypogonadism (e.g., due to hypothalamic, pituitary, or specific testicular disorder). If testosterone treatment does not alleviate symptoms of androgen deficiency after 3–6 months, it should be discontinued and other therapy considered. (2|++OO)

The Task Force suggests testosterone therapy for men at high risk for fracture with testosterone levels below 200 ng/dl (6.9 nmol/liter) who lack standard indications for testosterone therapy but who have contraindications to approved pharmacological agents for osteoporosis. (2|++OO)

Men with Prostate Cancer Receiving ADT

The Task Force recommends pharmacological treatment for osteoporosis for men with prostate cancer receiving ADT who have a high risk of fracture. (1|+++O)

Monitoring Therapy

The Task Force suggests that clinicians monitor BMD by DXA at the spine and hip every 1–2 yr to assess the response to treatment. If BMD appears to reach a plateau, the frequency of BMD measurements may be reduced. (2|+++O)

The Task Force suggests that clinicians consider measuring a bone turnover marker (BTM) at 3–6 months after initiation of treatment using a bone resorption marker (such as serum C-telopeptide of type I collagen [CTX] or serum or urine N-telopeptide of type I collagen [NTX]) for antiresorptive therapy and a bone formation marker (such as serum procollagen I N-propeptide [PINP]) for anabolic therapy. (2|+++O)

Definitions:

Quality of Evidence

+OOO Denotes very low quality evidence

++OO Denotes low quality evidence

+++O Denotes moderate quality evidence

++++ Denotes high quality evidence

Strength of Recommendation

1 - Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."

2 - Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Osteoporosis and osteoporosis-related fractures

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Nutrition

Orthopedic Surgery

Radiology

Rheumatology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To formulate practice guidelines for the management of osteoporosis in men

Target Population

Men at risk of osteoporosis:

- Higher risk men (aged ≥ 70)
- Men aged 50–69 who have risk factors (e.g., low body weight, prior fracture as an adult, smoking, etc.)

Interventions and Practices Considered

Evaluation/Risk Assessment

1. Assessment of risk factors for osteoporosis (age, fracture history, comorbidity, lifestyle)
2. Assessment of bone mineral density using dual-energy x-ray absorptiometry (DXA)
 - DXA of the spine and hip
 - Forearm DXA in certain cases
3. Complete patient history and physical examination
4. Laboratory evaluation (serum calcium, phosphate, creatinine [with estimated glomerular filtration rate], alkaline phosphatase, liver function, 25-hydroxyvitamin D [25(OH)D], total testosterone, complete blood count, and 24-h urinary calcium excretion)
5. Additional testing including calculated free or bioavailable testosterone, serum protein electrophoresis with free κ and λ light chains and/or urine protein electrophoresis, tissue transglutaminase antibodies (for celiac disease), thyroid function tests, and parathyroid hormone (PTH) levels
6. Vertebral fracture assessment

Treatment/Management

1. Lifestyle changes
 - Calcium and vitamin D supplementation
 - Increased weight-bearing exercise
 - Limiting alcohol
 - Smoking cessation
2. Pharmacological therapy for men at high risk for fracture
3. Selection of pharmacologic therapy
 - Bisphosphonates
 - Teriparatide
 - Denosumab
 - Testosterone
4. Considerations for management of hypogonadal men
5. Considerations for management of men with prostate cancer receiving androgen deprivation therapy (ADT)
6. Monitoring therapy using DXA and measuring a bone turnover marker

Major Outcomes Considered

- Predictive value of risk factors associated with osteoporosis and fracture
- Positive improvements in bone mass density (BMD) and other biochemical markers associated with bone health
- Reduction of fractures

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Description of Methods Used to Collect/Select the Evidence

The Endocrine Society's Task Force commissioned two systematic reviews (see the "Availability of Companion Documents" field) to support their guidelines on Osteoporosis in Men.

Risk Factors for Low Bone Mass-Related Fractures in Men: A Systematic Review and Meta-Analysis

Eligibility Criteria

Studies eligible for inclusion in this review were original articles describing analytic studies (observational cohort, case-control, or randomized controlled trials) that reported a relative risk measure (such as relative risk, odds ratio, or hazard ratio) for a risk factor (variables that increases risk) for bone loss or low bone mineral density (BMD)-related fractures in adult males.

Literature Search

An expert reference librarian and study authors with expertise in conducting systematic reviews developed the search strategy. Search was performed on MEDLINE and EMBASE through the Ovid interface; Cochrane CENTRAL, ISI Web of Science, and Scopus from 1950 through February 2010. Controlled vocabularies and text words were used for: 1) osteoporosis, bone density, bone resorption, osteolysis, and bone fractures; 2) testing for bone loss (low bone mass, BMD, dual-energy x-ray absorptiometry, bone loss, and bone turnover), screening; and 3) known risk factors (such as long-term usage of corticosteroids). In addition, terms indicating risk, such as "relative risk" and "odds ratio" were also included. The focus was on population, community, longitudinal, cohort, or observational studies as well as clinical trials, especially those including adult men. The same general strategy using text words was applied to Web of Science and Scopus. In addition, the authors reviewed the reference sections of eligible studies and available reviews and requested potentially eligible studies from content experts. The detailed search strategy used is available in the Supplemental Data (published on The Endocrine Society's Journals Online web site at <http://jcem.endojournals.org>).

Study Selection

Pairs of reviewers independently evaluated the eligibility criteria of titles and abstracts and of eligible full text articles using standardized and piloted electronic forms using an online reference management system (Distiller SR, Ottawa, Canada). Data extraction was done using similar methodology with adequate inter-reviewer agreement greater than 0.80.

Comparative Effectiveness of Drug Treatments to Prevent Fragility Fractures: A Systematic Review and Network Meta-Analysis

Eligibility Criteria

Trials eligible for inclusion in this review were: 1) randomized controlled trials; 2) trials that enrolled patients with established or at risk for osteoporosis; 3) trials that compared one or more of the interventions of interest to each other or to placebo; and 4) trials that measured the outcomes of interest, i.e., fragility fractures (vertebral, hip, and nonvertebral fractures). The interventions of interest were: bisphosphonates (alendronate, risedronate, zoledronate, and ibandronate), PTH 1-34 (teriparatide), selective estrogen receptor modulators (SERM) such as raloxifene or bazedoxifene, denosumab, and calcium and vitamin D. The task force decided to not include calcitonin because its fracture-preventing effect is generally considered to be very weak (5) and supported by low-quality evidence, and because it is not commonly used for modern long-term preventive therapy. Pamidronate, etidronate, strontium and lasofoxifene were also not included in this review because they are not approved by the Food and Drug Administration for the treatment of osteoporosis, the main focus of the guidelines.

Literature Search

An expert reference librarian and study authors with expertise in conducting systematic reviews developed the search strategy. An exploratory literature search identified recent and well-conducted systematic reviews about this topic. A previously published report that pooled data from trials that evaluated the effect of vitamin D and calcium on fractures was used as an index publication to identify these trials. Another previously published study also compared bisphosphonates, SERM, and PTH 1-34. The literature search of this latter study was updated through March 2010 because their search was done in November 2007. Subsequently, the literature search was updated through December 9, 2012. Additional searches were also conducted using the names of individual drugs as text words. MEDLINE and EMBASE were searched through the Ovid interface; the Cochrane Central Register of Controlled Trials (CENTRAL), ISI Web of Science, and Scopus were also searched. The search was not limited by sex of study participants included or language of the publication. In MEDLINE and EMBASE, the controlled hierarchical vocabularies (MeSH and Emtree) were used with the explode function to maximize sensitivity (osteoporosis, osteopenia, fractures, bone, bone

density conservation agents, and drug categories). The Cochrane validated search filter was employed for identifying randomized controlled trials in both MEDLINE and EMBASE. The MEDLINE search strategy was adapted to search EMBASE and CENTRAL using a combination of text words and subject headings. ISI Web of Science and Scopus were searched using only text words. Recent trials without fracture data and trials in which the drugs of interest were given to treat bone metastases were excluded. The latter group of studies was not within the scope of this review because enrolled patients did not necessarily have low bone mineral density and the outcomes were pathological rather than fragility fractures. A recent trial in which the majority of patients received bisphosphonate therapy for an average of 3 yr before the beginning of the trial was also excluded. The detailed search strategy is available in the Supplemental Data.

Study Selection

Pairs of reviewers independently evaluated eligibility of candidate titles and abstracts. When at least one reviewer determined an article was potentially eligible, the full text version was retrieved and pairs of reviewers assessed its eligibility. Standardized and piloted electronic forms using an online reference management system (Distiller SR, Ottawa, Canada) were employed.

Number of Source Documents

Risk Factors for Low Bone Mass-Related Fractures in Men: A Systematic Review and Meta-Analysis

The search identified 1251 candidate references, of which 55 studies were deemed eligible.

Comparative Effectiveness of Drug Treatments to Prevent Fragility Fractures: A Systematic Review and Network Meta-Analysis

A total of 116 studies provided data for the meta-analysis.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

+OOO Denotes very low quality evidence

++OO Denotes low quality evidence

+++O Denotes moderate quality evidence

++++ Denotes high quality evidence

Methods Used to Analyze the Evidence

Meta-Analysis

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Risk Factors for Low Bone Mass-Related Fractures in Men: A Systematic Review and Meta-Analysis

Quality Assessment

Reviewers appraised the quality of the included observational studies focusing on the adjustment for confounding, how study cohorts were selected, and how outcomes were assessed.

Meta-Analyses

Reviewers estimated odds ratios and 95% confidence intervals (CI) and pooled across studies using a random effect model. They quantified inconsistency using the I^2 statistic, which describes the proportion of heterogeneity across studies that is not due to chance, thus describing the extent of true inconsistency in results across trials. I^2 less than 25% and I^2 more than 50% reflect small and large inconsistency, respectively.

Subgroup and Sensitivity Analyses

To explore causes of inconsistency, subgroup analyses were specified *a priori* according to the following factors: 1) adequate adjustment to multiple risk factors [age and body mass index (BMI) at a minimum] *vs.* inadequate or no adjustment; 2) location of fracture site (hip, vertebrae, or other); and 3) hypogonadism type (drug-induced *vs.* not). Publication bias was assessed by inspecting funnel plots for each outcome and performing Egger's regression test.

Comparative Effectiveness of Drug Treatments to Prevent Fragility Fractures: A Systematic Review and Network Meta-Analysis

Data Extraction and Quality Assessment

Pairs of reviewers extracted data in duplicate, with disagreements resolved by discussion and consensus. Study selection and data extraction (focusing on judgment of quality indicators) had adequate chance-adjusted interreviewer agreement above 0.80. Reviewers evaluated the quality of trials using elements from the Cochrane risk of bias tool focusing on allocation concealment, blinding (patients, investigators, data collectors, and outcome assessors), outcome assessment, loss to follow-up (attrition), and the extent of prognostic balance of study arms at the start of the study. The quality of evidence was judged using the GRADE framework (Grading of Recommendations, Assessment, Development, and Evaluation).

Statistical Analysis

Direct head-to-head comparisons were conducted using a random effects model to estimate pooled odds ratios (OR) and 95% confidence intervals (CI) incorporating within- and between-study heterogeneity. Reviewers assessed publication bias by examining funnel plots symmetry and by conducting Egger's regression test. Heterogeneity was assessed using the I^2 statistic, which represents the proportion of heterogeneity that is not due to chance (but rather due to real differences across studies' populations and interventions). I^2 values over 50% indicate substantial heterogeneity. Direct comparisons were performed using the Comprehensive Meta-analysis version 2 software package (Biostat Inc., Englewood, NJ).

To incorporate indirect comparisons, reviewers conducted random-effects network meta-analyses using Markov chain Monte Carlo methods in WinBUGS 1.4.3 (MRC Biostatistics Unit, Cambridge, UK) following methods described by Lu and Ades. Reviewers modeled the comparative effectiveness of any two treatments as a function of each treatment relative to the reference treatment (i.e., placebo in this study). This approach assumes "consistency" of treatment effects across all included trials—that is, the direct and indirect estimates of effect for each pair-wise comparison do not disagree beyond chance.

Reviewers evaluated inconsistency by comparing the estimates from the direct comparisons and those from the indirect comparisons for the magnitude and direction of the point estimates and the extent of overlap of CI. The posterior distribution of all parameters was estimated using noninformative (i.e., vague, flat) priors to limit inference to data derived from the trials at hand (i.e., no assumptions were made about the efficacy of these drugs from data external to the 116 trials included in this systematic review). Reviewers updated three Markov chain Monte Carlo chains with 60,000 simulated draws after a burn in of 30,000 iterations using the same seed number (seed = 1000) for all chains. The pair-wise OR and 95% credible interval were reported and adjusted for multiple arm trials.

The probability that each drug was the most efficacious regimen was estimated by calculating the OR for each drug compared with an arbitrary common comparison drug (which was placebo in most cases due to the minimal number of head-to-head trials), and counting the proportion of iterations of the Markov chain in which each drug had the largest OR in reducing fracture risk.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Participants

The Task Force was composed of a chair, selected by the Clinical Guidelines Subcommittee of The Endocrine Society, five additional experts, and a methodologist.

Evidence

The Task Force used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and evidence quality.

Consensus

Consensus was guided by systematic reviews of evidence and discussions through a series of conference calls, e-mails, and one in-person meeting. An initial draft was prepared by the chair of the Task Force and was reviewed successively by The Endocrine Society's Clinical Guidelines Subcommittee and Clinical Affairs Core Committee; representatives of the American Society for Bone and Mineral Research (ASBMR), European Calcified Tissue Society (ECTS), European Society of Endocrinology (ESE), and International Society for Clinical Densitometry (ISCD); and members at large. At each stage, the Task Force received written comments and incorporated needed changes.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

1 - Indicates a strong recommendation and is associated with the phrase "The Task Force recommends."

2 - Denotes a weak recommendation and is associated with the phrase "The Task Force suggests."

Cost Analysis

The developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of the guideline were reviewed successively by The Endocrine Society's Clinical Guidelines Subcommittee and Clinical Affairs Core Committee; representatives of American Society for Bone and Mineral Research (ASBMR), European Calcified Tissue Society (ECTS), European Society of Endocrinology (ESE), International Society for Clinical Densitometry (ISCD); and members at large. At each stage, the Task Force received written comments and incorporated needed changes. The reviewed document was approved by The Endocrine Society Council before submission for peer review to the Journal of Clinical Endocrinology and Metabolism.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved identification, diagnostic evaluation and monitoring of men at risk of osteoporosis and fracture
- Reduction of fracture risk through lifestyle changes and pharmacological treatments

Potential Harms

- Because concomitant antiresorptive therapy seems to reduce the efficacy of teriparatide, increase costs, and expose patients to additional potential side effects, it should be discontinued when teriparatide is administered.
- Potential safety concerns with bisphosphonates include osteonecrosis of the jaw and atypical femur fractures
- A meta-analysis showed that calcium supplements may be associated with an increased risk of myocardial infarction but no other cardiovascular end points or death in women. This finding has not been confirmed in men. In older women, calcium supplementation increases the risk of kidney stones. The prevalence of kidney stones is higher in men than in women, but no increase in kidney stones has been demonstrated in men at the level of calcium intake recommended for optimal bone health. An observational study suggested that the risk of metastatic prostate cancer was higher in men who received high doses of supplemental calcium (1500–2000 mg/d), but this has not been substantiated in clinical trials.
- Vitamin D at high doses may result in toxicity (hypercalcemia or hypercalciuria), but this is rarely seen unless 25(OH)D levels exceed 150 ng/ml (375 nmol/liter), and such levels are unlikely with the doses of vitamin D recommended in the guideline. In a recent report of high-dose vitamin D (500,000 IU [12.5 mg] orally once a year) given to women older than 70 yr, there was an increased risk of fracture and falling, especially in the first 3 months after administration, when 25(OH)D levels were on average 50 ng/ml (125 nmol/liter). This finding needs to be confirmed in women and has not been documented in men, but it raises caution about giving high doses of vitamin D intermittently.

Contraindications

Contraindications

- Bisphosphonate therapy should not be used in men with impaired kidney function (estimated glomerular filtration rate ≤ 30 –35 ml/min).
- Teriparatide should not be used in men with prior irradiation. Full prescribing information should be consulted.

Qualifying Statements

Qualifying Statements

- Clinical Practice Guidelines are developed to be of assistance to endocrinologists and other health care professionals by providing guidance and recommendations for particular areas of practice. The Guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The Guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The Guidelines are not intended to dictate the treatment of a particular patient. Treatment decisions must be made based on the independent judgment of health care providers and each patient's individual circumstances.
- The Endocrine Society makes no warranty, express or implied, regarding the Guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Watts NB, Adler RA, Bilezikian JP, Drake MT, Eastell R, Orwoll ES, Finkelstein JS. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012 Jun;97(6):1802-22. [203 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Jun

Guideline Developer(s)

The Endocrine Society - Professional Association

Source(s) of Funding

The Endocrine Society

The Task Force received no funding or remuneration from commercial or other entities.

Guideline Committee

Osteoporosis in Men Task Force

Composition of Group That Authored the Guideline

Task Force Members: Nelson B. Watts (*Chair*); Robert A. Adler; John P. Bilezikian; Matthew T. Drake; Richard Eastell; Eric S. Orwoll; Joel S. Finkelstein

Financial Disclosures/Conflicts of Interest

The Endocrine Society maintains a rigorous conflict of interest review process for the development of clinical practice guidelines. All Task Force members must declare any potential conflicts of interest, which are reviewed before they are approved to serve on the Task Force and periodically during the development of the guideline. The conflict of interest forms are vetted by the Clinical Guidelines Subcommittee (CGS) before the members are approved by the Society's Council to participate on the guideline Task Force. Participants in the guideline development must include a majority of individuals without conflict of interest in the matter under study. Participants with conflicts of interest may participate in the development of the guideline but they have disclosed all conflicts. The CGS and the Task Force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined by remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (e.g., stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Completed forms are available through The Endocrine Society office.

Financial Disclosure of Task Force

Nelson B. Watts, M.D. (Chair)—Financial or Business/ Organizational Interests: American Association of Clinical Endocrinologists, International Society for Clinical Densitometry, OsteoDynamics; Journal of Clinical Endocrinology & Metabolism; Significant Financial Interest or Leadership Position: Amgen, Baxter, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Imagepace, Medpace, Merck, Pfizer/Wyeth, Warner Chilcott

Robert A. Adler, M.D.—Financial or Business/Organizational Interests: International Society of Clinical Densitometry; Significant Financial Interest or Leadership Position: Amgen, Eli Lilly, Genentech, Merck, Novartis, Virginia Commonwealth University

John P. Bilezikian, M.D.—Financial or Business/Organizational Interests: Endocrine Fellows Foundation, International Osteoporosis Foundation, GSK; Significant Financial Interest or Leadership Position: Amgen, Novartis, Merck, Warner-Chilcott, Eli Lilly, NPS Pharmaceuticals

Matthew T. Drake, M.D., Ph.D.—Financial or Business/Organizational Interests: KER unit (Mayo Clinic); Significant Financial Interest or Leadership Position: none declared

Richard Eastell, M.D., FRCP, FRCPath, FMedSci—Financial or Business/Organizational Interests: European Calcified Tissue Society, European Society of Endocrinology, International Bone and Mineral Society, Amgen, AstraZeneca, GSK, Medtronic, Natest, Nestle, Fonterra Brands, Novartis, Ono Pharma, Osteologix, Pfizer, Lilly, Sanofi-Aventis, Tethys, unilever, Unipath, Iverness Medical, Johnson & Johnson, SPD, MSD, IDS, Roche; Significant Financial Interest or Leadership Position: Amgen, Novo Nordisk, Pfizer, Sanofi-Aventis

Eric S. Orwoll, M.D.—Financial or Business/Organizational Interests: Merck, Lilly, Amgen, Wright; Significant Financial Interest or Leadership Position: American Society for Bone and Mineral Research, International Osteoporosis Foundation

Joel S. Finkelstein, M.D.—Financial or Business/Organizational Interests: Astra Zeneca, Solvay Pharmaceuticals, Abbott, Up-to-Date; Significant Financial Interest or Leadership Position: none declared

Guideline Endorser(s)

American Society for Bone and Mineral Research - Professional Association

European Calcified Tissue Society - Professional Association

European Society of Endocrinology - Medical Specialty Society

International Society for Clinical Densitometry - Nonprofit Organization

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from [The Endocrine Society](#) .

Print copies: Available from The Endocrine Society, Phone: (301) 941.0210; Email: SocietyServices@endo-society.org

Availability of Companion Documents

The following are available:

- Murad MH, Drake MT, Mullan, RJ, Mauck KF, Stuart LM, Lane, MA, Abo Alhour NO, Erwin PJ, Hazem A, Puhon MA, Li T, Montori VM. Comparative effectiveness of drug treatments to prevent fragility fractures: a systematic review and network meta-analysis. J Clin Endocrinol Metab. 2012 Jun;97(6):1871-80. Electronic copies: Available to subscribers from [The Journal of Clinical Endocrinology & Metabolism \(JCEM\) Web site](#) .
- Drake MT, Murad MH, Mauck KF, Lane MA, Undavalli C, Elraiyah T, Stuart LM, Prasad C, Shahrour A, Mullan RJ, Hazem A, Erwin PJ, Montori VM. Risk factors for low bone mass-related fractures in men: a systematic review and meta-analysis. J Clin Endocrinol Metab. 2012 Jun;97(6):1861-70. Electronic copies: Available to subscribers from [The JCEM Web site](#) .

Print copies: Available from The Endocrine Society, Phone: (301) 941.0210; Email: SocietyServices@endo-society.org

Patient Resources

None available

NGC Status

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